

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/25/2008 has been entered. Claims 1-22 are pending in this application. Claims 4 and 11 are withdrawn from consideration.

***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 08/26/2008 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 3, 5, 9-10, and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al., hereinafter **Green** (U.S. Patent No. 5,674,231) in view of Mikus et al., or **Mikus** (U.S. Patent No. 6,517,569).

Claims 1, 17, 19, 20, and 22: Green discloses a method for delivering a closure element in a blood vessel **104**, the closure element being carried by a carrier assembly **42** slideable on an outer surface of an elongate member **30**, the elongate member comprising and at least partially overlying the carrier assembly, the elongate member being provided with a locator member **60** slidably associated therewith, the locator member having one or more expandable positioning elements **62, 64** on its distal portion, the method comprising inserting the distal end of the elongate member into an opening through tissue, advancing the locator member distally from the distal end of the elongate member, expanding the one or more positioning elements, withdrawing the locator member until the positioning elements contact tissue, advancing the carrier assembly towards the distal end of the elongate member, and deploying the closure element from the carrier assembly within the opening to substantially seal the opening (Figures 1-4, 7, 10-11 and col. 5, lines 45-67, col. 6, lines 1-8, col. 7, lines 18-67, col. 8, lines 1-52).

Green discloses the claimed invention except for a skin, or sleeve member, overlying at least a portion of the outer surface between the carrier assembly and a distal end of the elongate member and the carrier assembly causing the skin to separate from the outer surface of the elongate member as the carrier assembly is advanced towards the distal end.

Mikus teaches a skin or sleeve **20** overlying at least a portion of an outer surface between a carrier assembly **30, 50** and a distal end of an elongate member **15** and the carrier assembly may cause the skin to separate or split from the outer surface of the elongate member from a proximal end of the skin toward a distal end of the skin when the carrier assembly is advanced (Figures 1, 3-4 and col. 3, lines 13-29 and col. 5, lines 28-40). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Green with a splittable skin, as taught by Mikus, since it was known in the art that skins or sheaths are commonly used in deployment devices to conveniently protect delivery devices and are often subsequently opened or removed in order to unveil the delivery device without additional manipulation by a secondary instrument.

Claim 2: Green discloses removing the elongate member from the opening (col. 8, lines 44-52).

Claims 3 and 5: Green discloses the claimed invention, except for the skin comprising a weakened region extending towards the distal end of the elongate member, the weakened region tearing as the carrier assembly is advanced towards the distal end of the elongate member, and the skin expanding to a cross-section that is larger than a

cross-section of the elongate member as the carrier assembly is advanced towards the distal end.

Mikus teaches the skin **20** comprising a weakened region **22** extending towards the distal end of the elongate member, the weakened region tearing as the carrier assembly is advanced towards the distal end of the elongate member, and the skin expanding to a cross-section that is larger than a cross-section of the elongate member as the carrier assembly is advanced towards the distal end (Figures 1 and 3-4). It would have been obvious to one of ordinary skill in the art to provide a skin with a weakened region, as taught by Mikus, to Green since it was known in the art that skins or sheaths are commonly used in deployment devices to protect delivery devices with weakened regions to serve as a simple opening mechanism that does not require a second instrument.

Claim 9: Green discloses the opening through tissue communicating with a blood vessel, and wherein the deploying step comprises substantially sealing the opening from blood flow therethrough with the closure element. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 10: Green discloses coupling the carrier assembly to a proximal end of the elongate member. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 14: Green discloses contracting said positioning elements and withdrawing said locator member. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 15: Green discloses the distal end of the elongate member being inserted into the lumen of a blood vessel and wherein the positioning elements of the locator member

are expanded within the lumen of a blood vessel. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 16: Green discloses the step of withdrawing the locator member causes the positioning elements to come into contact with the wall of the blood vessel. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claims 18 and 21: Green and Mikus disclose the claimed invention except for the blood vessel being the femoral artery. It would have been obvious to one of ordinary skill to provide the blood vessel as being a femoral artery in Green and Mikus, since it was known in the art that the femoral artery is a blood vessel and that the vascular hole closure device and method may be applied to any blood vessel.

5. Claims 7-8 and 12-13 rejected under 35 U.S.C. 103(a) as being unpatentable over **Green** (U.S. Patent No. 5,674,231) in view of **Mikus** (U.S. Patent No. 6,517,569), as applied to claim 1 above, and further in view of **Martinez** (U.S. Patent No. 5,593,412).

Claim 7: Green and Mikus disclose the claimed invention, except for the skin comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue.

Martinez teaches the skin comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue and that it allows for retraction of the sheath and allows for expansion for the element onto which it is disposed (col. 3, lines 30-42 and col. 4, lines 53-67 and col. 5,

lines 1-2). It would have been obvious to one of ordinary skill to provide a skin with a slippery outer surface, as taught by Martinez, to Green and Mikus since it was known in the art that a lubricated, slippery surfaces allow for facilitated translational movement and also in order to allow for expansion of the elongate member or the element onto which it is disposed.

Claim 8: Green and Mikus disclose the claimed invention except for the opening through tissue extending through one or more layers of fascia, and wherein the skin facilitates advancement of the carrier assembly through the one or more layers of fascia. It would have been obvious to one of ordinary skill in the art for the skin to facilitate advancement of the carrier assembly through one or more layers of fascia, or connective tissues of the blood vessel, in Green and Mikus, since it was known in the art that sheaths and skins protect as well as facilitate advancement of deployment devices through layers of tissue in the surgical site.

Claims 12-13: Green and Mikus disclose the claimed invention except for the skin comprising a plurality of longitudinal slots, the slots opening as the carrier assembly is advanced, thereby expanding the skin, and the slots being staggered relative to one another such that the skin assumes a zigzag mesh configuration as it expands.

Martinez teaches a skin comprising a plurality of longitudinal slots, the slots opening as the carrier assembly is advanced, thereby expanding the skin, and the slots being staggered relative to one another such that the skin assumes a zigzag mesh configuration as it expands (Figures 1-5 and col. 4, lines 53-67 and col. 5, lines 1-2). It would have been obvious to one of ordinary skill in the art to provide a skin having a

plurality of slots assuming a zigzag mesh configuration, as taught by Martinez, to Green and Mikus since it was known in the art that this configuration allows for more flexibility and lateral, axial, and longitudinal expansion.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Green** (U.S. Patent No. **5,674,231**) in view of **Mikus** (U.S. Patent No. **6,517,569**), as applied to claim 1 above, and further in view of Kanner et al., hereinafter **Kanner** (U.S. Patent No. **5,868,755**).

Claim 6: Green and Mikus disclose the claimed invention except for the skin being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin is peeled away from the outer surface as the carrier assembly is advanced towards the distal end.

Kanner teaches a skin **1** being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin is peeled away from the outer surface as the carrier assembly is advanced towards the distal end (col. 4, lines 1-16). It would have been obvious to one of ordinary skill in the art to provide a skin bonded to the outer surface to the elongate member, as taught by Kanner, to Green and Mikus, since it was known in the art to provide adhesives that provide temporary security and to avoid undesired movement of the sheath.

***Response to Arguments***

7. Applicant's arguments filed 08/25/2008 have been fully considered but they are not persuasive.
8. Applicant generally argues that Mikus teaches the reverse of what is recited in the claims regarding advancing the carrier assembly causes the skin to separate from a proximal end of the skin toward a distal end of the skin, and there is no need to modify Green since a sleeve 100 is already present. However, it is possible in Mikus that the advancement of the carrier assembly 30 may cause proximal to distal tearing of the skin 20 at the time of deployment of the device after the restrainers have been removed and if the stent or device (or clip 22 in Green) being deployed is of a significant diameter that would cause tearing of the sheath. The combined teachings of Mikus and Green would suggest to one skilled in the art a modified retraction of a skin or sleeve that protects the device in order to unveil the delivery device without an additional mechanism or secondary device.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731